510(K) Summary

CarboFix Orthopedics Ltd.

Piccolo Composite® Nailing Systems

Applicant Name

CarboFix Orthopedics Ltd.

11 Ha'hoshlim St., Herzeliya 46724, Israel

Contact Person

Yael Rubin

CarboFix Orthopedics Ltd.

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OCT 0 3 2013

Date Prepared

September 2013

Trade/Proprietary Name

Piccolo Composite® Nailing System

Common Name

Intramedullary Nailing System

Classification Name

Rod, Fixation, Intramedullary and Accessories (Class II, per 21 CFR §888.3020; Product Code HSB)

Predicate Devices

- Piccolo Composite® Nailing Systems (CarboFix Orthopedics Ltd.; K091425, K100497, K102369, K111056, K123810)
- Piccolo Composite® Plate Systems (CarboFix Orthopedics Ltd.; K130061, and more)

Intended Use/Indications for Use

Piccolo Composite Humeral, Proximal Humerus, Tibial and Femoral Nails

Indications include simple fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathological fractures; reconstruction, following tumor resection and grafting. The nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

Piccolo Composite Ankle Arthrodesis Nails

Indicated for tibiotalocalcaneal arthrodesis (fusion). Specific indications include:
Avascular necrosis of the talus; Failed total ankle arthroplasty; Trauma (malunited tibial pilon fracture); Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease; Revision ankle arthrodesis; Neuroarthropathy; Rheumatoid arthritis; Osteoarthritis; Pseudoarthrosis; Post-traumatic arthrosis; Previously infected arthrosis; Charcot foot; Severe endstage degenerative arthritis; Severe defects after tumor resection; Pantalar arthrodesis

System Description

The Piccolo Composite Nailing Systems include nails, interlocking screws and instrumentation sets.

The nails are made, in general, of carbon fiber reinforced polyetheretherketone (CFR-PEEK), and are marked with tantalum markers, to provide for their visualization under fluoroscopy. The nails provide for holes at the proximal and distal sections, designed for the insertion of the titanium-alloy-made screws.

There is no change to the general description of the system as compared to the predicate devices.

Substantial Equivalence

The Piccolo Composite Nailing Systems intended use, design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.

Evaluation of expected performance characteristics and MR Conditional labeling parameters for the Piccolo Composite Nailing Systems was based on comparison to predicate devices. All the above demonstrate that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

CarboFix Orthopedics Limited
Ms. Yael Rubin
Director of Regulatory Affairs
11 Ha'hoshlim Street
Herzeliya, 46724
ISRAEL

Re: K132774
Trade/Device Name: Piccolo Composite® Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 1, 2013
Received: September 5, 2013

Dear Ms. Rubin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): _____

Device Name: Piccolo Composite® Nailing System

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Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices